

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/28591

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : G01N 33/53, 33/567, 33/555; A01K 67/00, 67/033

US CL : 435/7.2, 7.21, 7.24, 29; 800/13

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/7.2, 7.21, 7.24, 29; 800/13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST; Chemical Abstracts

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,432,059 A (BEAN et al) 11 July 1995, col. 2, 63-64; col. 7, lines 1-11	1-37 and 48-51
Y	PALMERINI et al. A Fluorescent Assay for the Determination of UDP-GlcNAc: Gal $\beta$ 1,3GalNAc (GlcNAc to GalNAc) $\beta$ 1,6N-Acetylglucosaminyltransferase Activity. Analytical Biochemistry. 1995, Vol. 225, pages 315-320, see especially 316-319.	1-37 and 48-51
Y	DATTI et al. A Coupled Assay for UDP-GlcNAc:Gal $\beta$ 1-3 GalNAc-R $\beta$ 1,6-N-Acetylglucosaminyltransferase (GlcNAc to GalNAc). Analytical Biochemistry. 1992, Vol. 206, 262-266, see especially 263-265.	1-37 and 48-51



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

29 FEBRUARY 2000

Date of mailing of the international search report

17 MAR 2000

Name and mailing address of the ISA/US  
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international application No.  
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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	NIEHUES et al. Carbohydrate-Deficient Glycoprotein Syndrome Type Ib. Journal of Clinical Investigation. April 1998, Vol. 101, No. 7, pages 1414-1420, see especially pages 1415-1418.	1-37 and 48-51
Y	CAMPELL et al. Complex Asparagine-Linked Oligosaccharides in Mgat1-Null Embryos. Glycobiology. 1995, Vol. 5, No. 5, pages 535-543, see especially pages 536-541.	38-47
Y	HENNET et al. T-Cell-Specific Deletion of a Polypeptide N-Acetylgalactosaminyl-Transferase Gene by Site-Directed Recombination. Proceedings of the National Academy of Science, USA. December 1995, Vol.92, pages 12070-12074, see especially pages 12073 and 12074.	38-47
Y	ANTON et al. Two Methods of Measuring Carbohydrate-Deficient Transferrin in Inpatient Alcoholics and Healthy Controls Compared. Clinical Chemistry. 1994, Vol. 40, No. 3, pages 364-368, see especially.	38-47

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## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

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## BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

Group I, claim(s) 1-23, 26-37 and 48-51, drawn to methods of diagnosing a glycosylation disorder and a kit for diagnosing a glycosylation disorder.

Group II, claim(s) 24 and 25, drawn to methods of monitoring.

Group III, claim(s) 38-47, drawn to chimeric and transgenic nonhuman mammals.

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Mice were known in the art at the time of filing which comprised a defect in the  $\beta$ -1,4-galactosyltransferase gene (Lu et al (1997) Developmental Biology 181, 257-267, abstract). Thus, the mice of Lu et al indicate that the invention lacks a special technical feature as such a feature was known in the art at the time of filing. Thus, there is no inventive concept to the claimed invention under PCT Rule 13.2.